DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

M3097N

San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

Via Federal Express 4165 0457 1760
Our Reference: 29- 50881

Warning Letter

October 22, 1999

Deborah Sorgnard
President and CEO
Matrix Biokinetics, Inc.
6741 West Alexander Rd.
Las Vegas, NV 89030

Dear Ms. Sorgnard:

I have received correspondence dated September 8, September 14, and October 6, 1999 from Ms. Paula Cox of your firm. The correspondence attempts to address observations made by our investigator during an inspection of September 2, 1999. That inspection was made as a follow-up to a warning letter which had issued to you on July 1, 1998 regarding your firm's failure to fully comply with FDA's Quality System Requirement (QSR), as delineated under 21 Code of Federal Regulations, Part 820.

The material submitted by Ms. Cox has been reviewed. Based upon that review, it has been determined that your firm continues to fail to satisfy important requirements of the QSR. I offer the following comments to the issues that are of particular concern:

1. Ms. Cox's correspondence of September 8, 1999 advises that, in response to item #1 of the FDA483, you are named as QA Manager, with Mr. (David) Cameron Quigley acting in your absence. It is unclear from the letter whether Mr.Quigley is intended to serve in your absence as an individual with executive responsibility, per 21 CFR 820.20(a), or whether he is serving as your management representative who is responsible for ensuring that the quality system requirements are fulfilled by your firm, per 21 CFR 820.20(b)(3). Please provide clarification of this issue.

2. Neither the correspondence of September 8, 1999 nor that of September 14, 1999 addresses FDA483 item #3 regarding the lack of procedures for investigation of the root cause of nonconforming products (no corrective and preventative action procedure). Implementation of such a procedure is a requirement of 21 CFR 820.100.

3. In her correspondence, Ms. Cox has not addressed corrective actions taken in response to FDA483 item #4 regarding investigation of complaints. The Complaint Reports that are included in the letter of September 8, 1999 do not provide the results of investigation by your QA unit. Those reports merely document that parts were replaced or repaired, without addressing and investigation into the cause for your devices' failure to meet performance specifications. Such investigation is a requirement of 21 CFR 820.198. If you now have additional documentation regarding complaint investigation, please forward them for review.

   Also, your new Customer Service and Complaint Handling Procedure of September 3, 1999 makes no mention of criteria which distinguish between complaints and "noncomplaints". I notice that several of the examples submitted with your letter classify contact by a customer as a "noncomplaint", yet note that the units exhibited dosage problems.

4. In Ms. Cox's correspondence of October 6, 1999, she requested an extension until October 15, 1999 to submit your firm's quality plan (e.g., policy). To this date, we have not received this document. A quality plan is a requirement of 21 CFR 820.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA483 issued to you at the end of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions. We note that observations from the previous inspection in 1998 have not been completely corrected. You are responsible for investigating and determining the causes of the violations.

You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and/or civil penalties.

Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts. Additionally, requests for Certificates of Exportability and Certificates to Foreign Governments will not be cleared until the violations related to the subject devices have been corrected.

In order to help FDA make the determination that corrections have been made, enabling FDA to withdraw its advisory to other federal agencies concerning the awarding of government contracts, and to resume export clearance for products manufactured at your facility in Las Vegas, NV, we are requesting that you submit certification by an outside

expert consultant that he/she has conducted an audit of your firm's manufacturing and quality assurance systems, relative to the requirements of the QSR. Please submit a copy of the consultant's report, and your personal certification that you have reviewed the report, showing that your firm has initiated or completed all corrections called for in the report. Also provide information regarding the qualifications of your consultant, and verification that his/her services have undergone the vendor qualification process required under 21 CFR Part 820.50.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems as necessary to assure that similar violations will not recur. If corrective actions cannot be completed within 15 working days, state the reason for the delay and the date on which the corrections will be completed.

Your response should be sent to the following:

Andrea P. Scott
Compliance Officer
U. S. Food and Drug Administration
96 North Third St., Suite 325
San Jose, CA 95112

Sincerely,

Patricia C. Ziobro

Patricia C. Ziobro
Director
San Francisco District

Cc: Paula Cox